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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/359,300	KUMAGAI ET AL.	
	Examiner	Art Unit	
	Gerald G Leffers Jr.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 11 June 2001.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 45 and 58-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 45 and 58-70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- |  |  |
|--|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____   |
| 16) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                         | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>16</u> | 20) <input type="checkbox"/> Other   |

## DETAILED ACTION

Receipt is acknowledged of applicants' amendment, filed 6-12-01 as Paper No. 18, wherein certain claims were cancelled (claims 46-57) and other claims were amended (45, 58-59, 61, 65 and 67-70). Claims 45 and 58-70 are pending in this application.

Receipt is also acknowledged of an information disclosure statement filed 3/21/01 as Paper No. 16. The signed and initialed PTO Form 1449 has been mailed with this action.

Any rejection of record in Paper No. 15 not addressed in this action has been withdrawn. Because applicants' amendments to the claims necessitated the new rejections made in this action, this action is FINAL.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 45 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 43 of copending Application No. 09/359,305. Although the conflicting claims are not identical, they are

not patentably distinct from each other. **This rejection is maintained for reasons of record in Paper No. 15.**

Claim 45 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 43 of copending Application No. 09/359,297. Although the conflicting claims are not identical, they are not patentably distinct from each other. **This rejection is maintained for reasons of record in Paper No. 15.**

Claims 45 and 58-70 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 41, 43-45 and 57 of copending Application No. 09/359,301. Although the conflicting claims are not identical, they are not patentably distinct from each other. **This rejection is maintained for reasons of record in Paper No. 15.**

These are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

#### ***Response to Arguments***

Applicant's arguments filed in Paper No. 18 have been fully considered but they are not persuasive. Applicants' response indicates that applicants will address the provisional obviousness double-patenting rejections upon the indication of allowable subject matter in the instant application. The rejections are maintained.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45 and 58-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 is vague and indefinite in that the metes and bounds of the phrase "functional gene profile" are unclear. **This is a new rejection necessitated by applicants' amendment to claim 45 in Paper No. 18.**

The phrase is defined in the specification (page 35, lines 3-12) as "The collection of genes of an organism which codes for a biochemical or phenotypic trait. The functional gene profile of an organism is found by screening nucleic acid sequences from a donor organism by over expression or suppression of a gene in a host organism. A functional gene profile requires a collection or library of nucleic acid sequences from a donor organism. A functional gene profile will depend on the ability of the collection or library of donor nucleic acids to cause over-expression or suppression in the host organism. Therefore, a functional gene profile will depend upon the quantity of donor genes capable of causing over-expression or suppression of host genes or of being expressed in the host organisms in the absence of a homologous host gene.". It is unclear from the claim language and from the definition given in the specification as to how many of the possible genes in an organism which "code" for a biochemical or phenotypic trait are required to be characterized by the claimed methods before a "profile" has been obtained. Would identification of only 2 genes of the many possible genes in either the host or donor organism which are associated with the determined phenotypic or

biochemical change due to overexpression of heterologous nucleic acids in the host satisfy the criteria for a functional gene "profile" for that organism?

The definition states that the functional gene profile will depend upon the quantity of donor genes capable of causing over-expression or suppression of host genes or of being expressed in the host organism in the absence of a homologous host gene, implying that the number of genes that needs to be characterized in order to generate a functional gene profile are all of the genes from an organism, host and/or donor, which are associated with a phenotypic or biochemical change due to expression of heterologous nucleic acids in the host. Would a "functional gene profile" be generated only when all of the genes from a donor or host organism are identified which are associated with a biochemical or phenotypic change upon expression of a heterologous nucleic acid in the plant host? If so, how would one know when all of the genes from either the host or donor organism associated with the biochemical or phenotypic change have been identified and the claim limitation met? It would be remedial to amend the claim language to clearly indicate how many of the possible genes from a donor or host organism associated with the determined phenotypic or biochemical change need to be identified in order to satisfy the claim limitation of being a "functional gene profile".

Claim 45 is vague and indefinite in that there is no clear and positive prior antecedent basis for the phrase "said one or more changes" in step (e). **This rejection is maintained for reasons of record in Paper No. 15.**

### *Response to Arguments*

Applicant's arguments filed in Paper No. 18 with regard to rejection of claim 45 for lack of prior antecedent basis for the phrase "said one or more changes" have been fully considered but they are not persuasive. Applicants' response asserts that proper antecedent basis exists for the cited phrase in step (d). This assertion is inaccurate. It would be remedial to amend the claim language at that step to read "said one or more phenotypic or biochemical changes".

Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. **This is a new rejection necessitated by applicants' amendment to the claims in Paper No. 18.** The omitted steps are: any step of identifying a donor gene or plant host gene associated with the observed phenotypic or biochemical change. The final step of the claims comprises the limitation of "...repeating steps (b)-(f) until a positive sense functional gene profile of said plant host or said donor organism is compiled.", yet there is no step recited in the claim for identifying donor or host genes associated with the observed biochemical or phenotypic gene.

Claims 58-59 are vague and indefinite in that there is no clear and positive prior antecedent basis for the phrase "said changes" in claim 45, upon which both claims are dependent. **This is a new rejection necessitated by applicants' amendment to the claims in Paper No. 18.** It would be remedial to amend the claim language to "said phenotypic or biochemical changes.

### *Conclusion*

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

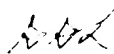
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. §1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald Leffers, Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than 24 hours after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Rob Schwartzman, Ph.D., can be reached at (703) 308-7307.

Any inquiry of a general nature or relating to the status of this application, or relating to attachments to this office action, should be directed to the Patent Analyst Zeta Adams, whose telephone number is (703) 305-3291.

  
G. Leffers Jr., Ph.D.  
Patent Examiner  
Art Unit 1636  
13 July 2001

DAVID GUZO  
PRIMARY EXAMINER  
